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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,220	06/22/2000	Alfred H. Dougan	4045-0109P	7800

2292 7590 11/29/2002

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EXAMINER

MCGARRY, SEAN

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 11/29/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/599,220

Applicant(s)

DOUGAN ET AL.

Examiner

Sean R McGarry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 18 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 9/18/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "a protein having a half-life in serum of greater than 1.5 hours" in claim 16. It is noted that page 7 appears to provide support for half-life spans but not that instantly amended into claim 16. It is also noted that applicant has not provided support in the specification for the amendments made to the claims as required under 37 CFR 1.111, see MPEP 714.02 and 2163.06, for example.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claims 16, 18-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. See the new matter objection above.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instantly claimed invention is broadly drawn to include any and all oligonucleotides that may bind to any and all proteins that may be a component of a mammalian clotting cascade and also includes any and all proteins that may be bound to the 3' and/or 5' end of the oligonucleotide.

The instant specification discloses two aptamer oligonucleotides that were known in the art at the time of invention (see US 5,756,291, for example) that bind to thrombin where streptavidin or biotin was conjugated to the 3' and/or 5' ends. The disclosure of these two known sequences with biotin or streptavidin conjugated to the 3' and/or 5' end does not allow one in the art to immediately envision the structure of other oligonucleotide aptamers that bind to different proteins that may be a component of a mammalian blood clotting cascade which have been complexed with any protein at the 3' and/or 5' end. The instant disclosure of two species is clearly not representative of the genus instantly embraced in the claims. The members of the genus are highly divergent since each aptamer oligonucleotide varies in sequence and such sequences are not predicable but must be found de novo for each and every target protein (see US 5,756,291, for example). Each aptamer has different properties. The instant invention is therefore lacking an adequate written description.

Applicant's arguments filed 9/18/02 have been fully considered but they are not persuasive.

Applicant argues that the instant invention is drawn to the end modification of an aptamer by a protein with the result that the half-life of the aptamer in circulation is extended and asserts that the specification adequately describes the common structural feature, i.e. modification of the 5' or 3' end of a nucleic acid by a protein and that the particular sequence of the aptamer is not particularly relevant to the instant invention. It is noted that the claimed invention is as described by applicant with the addition requirement that the nucleic acid binding to a blood clot or a blood protein and that the protein have a half life of greater than 1.5 hours. It is noted that the sequence of a nucleic acid that will act as an aptamer and bind to a blood clot or a particular blood protein is very much a relevant feature of the claimed invention since the nucleic acid must be able to bind to such proteins and further the capability of such nucleic acids to bind is based on their structure (i.e. sequence). Applicant asserts that "a large number of variations of the nucleotide sequence aptamers that bind to at least the blood clotting protein thrombin are well known in that art and thus need not be described in detail in the specification. Applicant provides no evidence to support this assertion. Further it appears that this argument is directed only to variations of those two aptamers disclosed in the specification and which were addressed in the rejection of record. It is noted that applicant has not addressed the new claims 16-27 (as required under 37

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CFR1.111) and why they would not be so rejected (as required under 37 CFR1.111) and they are rejected for the reasons of record.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 **were** rejected under 35 U.S.C. 103(a) as being unpatentable over Griffin et al [US 5,756,291], Boado et al [Bioconjugate Chem., Vol. 3:519-523, 1992, cited by applicant]. This rejection is withdrawn in view of the amendment made to the claims 9/18/02.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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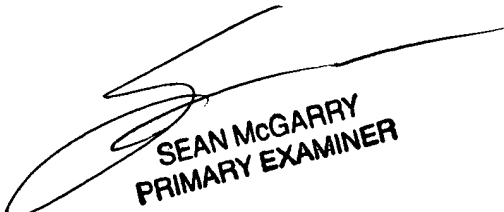
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (703)305-7028. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

srm
November 26, 2002



SEAN MCGARRY
PRIMARY EXAMINER